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| 10/572,737 | 03/21/2006 | Wael Mohamed Nabil Lotfy | SAI-003.01 | 6907 |

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FOLEY HOAG, LLP
PATENT GROUP, WORLD TRADE CENTER WEST
155 SEAPORT BLVD
BOSTON, MA 02110

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| EXAMINER |
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SHARMA, YASHITA

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| ART UNIT | PAPER NUMBER |
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3774

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11/10/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/572,737 | Applicant(s) LOTFY, WAEI MOHAMED NABIL | |
| | Examiner YASHITA SHARMA | Art Unit 3774 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-31 is/are pending in the application.
- 4a) Of the above claim(s) 29-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/15/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of claims

1. This office action is responsive to the preliminary amendment filed on 07/15/2009. As directed by the amendment: claims 1-18 have been cancelled and new claims 19-31 have been added. Thus, claims 19-31 are presently pending in this application.

Election/Restrictions

2. Newly submitted amended claim 29 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the amended claims now require a method of regulating blood flow in a blood vessel.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 29-31 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Amendment

3. The amendment filed 07/15/2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "the ball is free to

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move inside the stent, and contact of the ball against the inflatable," as set forth in claim

1. The original disclosure in the original specification does not provide support for the lining of the stent being on the inside where it lines the stent and defines the orifice on the distant end of the stent. The original disclosure had a "lined inflatable and dilatable valved balloon stent (the stent is dilatable and its lining is either inflatable or dilatable."

According to this description, the stent could be lined with an inflatable lining on the outside of the stent to abut against the blood vessel to prevent any damage to an aneurysm or any other problems. The lining defining the stent and the orifice where the ball contacts against the lining and blocks fluid or gas flow through the distal end of the stent is new matter and was not supported in the original specification.

4. Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 19-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rucker (2006/0167538) in view of Pavcnik et al. (5,397,351).**

7. Regarding claims 19 and 23, Rucker discloses a dilatable, inflatable (pg. 1, par. 0013) stent 10 having a proximal end and a distal end (the left and right ends; Fig. 2); an orifice (inner surface 16 and lumen 14; Fig. 3) at the distal end of the stent (Fig. 3),

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the orifice having a size (Fig. 3 shows the size of the orifice defined by the inner surface 16 and lumen 14), an inflatable lining 30 (Figs. 2 and 3) that lines the stent and defines the size of the orifice (the inflatable reservoir 30 lines the entire stent and defines the lumen opening created by inner surface 16); except for a ball valve having a cage-shaped barrier covering the proximal end of a stent; an inflatable ball having a size larger than the orifice size, the ball trapped in the stent by the cage-shaped barrier and the orifice; wherein the ball is free to move inside the stent, and contact of the ball against the inflatable lining blocks fluid or gas flow through the distal end of the stent.

8. However, Pavcnik teaches a similar invention comprising a ball valve 10 (Fig. 1) having an orifice (ring 14; Fig. 1), cage-shaped barrier 12 (Fig. 1) covering the proximal end of a stent 20 (Fig. 1); an inflatable ball 18 (col. 4, lin. 32-33; Fig. 1) having a size larger than the valve orifice (ring 14; Fig. 1) size (as shown in Fig. 1), the ball trapped in the stent by the cage-shaped barrier and the orifice (as best seen in Fig. 1); wherein the ball is free to move inside the stent (Fig. 1), and contact of the ball against the inflatable lining of Rucker will inherently blocks fluid or gas flow through the distal end of the stent.

9. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the inflatable lining lined stent in Rucker to include a ball valve having a cage-shaped barrier covering the proximal end of a stent; an inflatable ball having a size larger than the orifice size, the ball trapped in the stent by the cage-shaped barrier and the orifice; wherein the ball is free to move inside the stent, and contact of the ball against the inflatable lining blocks fluid or gas flow through the

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distal end of the stent, for the purpose of allowing a one way flow of the blood inside the blood vessel while preventing any blockages or damage to the blood vessels.

10. Regarding claim 20. Rucker discloses the lining is compressible (pg. 1, par. 0013).

11. Regarding claims 21 and 22, Rucker discloses the stent is made of metallic material (pg. 1, par. 0006) and the stent is made of plastic material (pg. 2, par. 0031).

12. Regarding claims 24-26, Rucker discloses the stent is shaped as a ring (Fig. 3), the stent is of tubular shape (Figs. 2 and 3), the stent is of cylindrical shape (Figs. 2 and 3).

13. **Claim 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rucker (2006/0167538) in view of Pavcnik et al. (5,397,351) further in view of Pavcnik et al. (2001/0011187).** Rucker discloses the claimed invention; except for the stent is of conical and pentagonal shape. However, Pavcnik discloses a similar stent comprising conical shape (Fig. 1 of '351). Furthermore, Pavcnik discloses a stent comprising pentagonal shape (pg. 2, par. 0026 of '187). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the stent in Rucker to include a conical and pentagonal shape, for the purpose of allowing the stent to closely conform to the shape of the surrounding tissue.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YASHITA SHARMA whose telephone number is (571)270-5417. The examiner can normally be reached on Monday - Thursday, 8 am to 4 pm EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Y. S./

Examiner, Art Unit 3774

/Thomas J Sweet/

Primary Examiner, Art Unit 3774